The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

April 7-8, 2003 – Meeting #6

Day 1 – April 7, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on April 7, 2003, at the Pikesville Hilton in Pikesville, Maryland for its sixth meeting. Shortly after 9:00 a.m., Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order and distributed the sign in sheet (Attachment 6.1). Ms. Sylvester informed the committee that member Leslie Lloyd from the American Occupational Therapy Association and her husband became parents to a little girl on April 4, 2003. The first item on the day's agenda (Attachment 6.2) was to review and approve the minutes from the last meeting. Of significance was a comment from Cathy Ellis, American Physical Therapy Association (APTA), that a statement on page 5 of the minutes relating information shared by co-member Kim Doolan, Barr Foundation, on the nature and source of infractions/complaints being handled by the Texas Council of Physical and Occupational Therapists and the Board of Orthotics and Prosthetics could be misinterpreted. At the conclusion of additional comments and notification of edits, the minutes were approved as noted (Attachment 6.3). After hearing various committee members' preferences on the order that items should be addressed on the day's agenda, Ms. Sylvester decided that the next order of business would be to hear responses to a question previously posed by Kim Doolan to the American Board of Certification (ABC), Board for Orthotist/Prosthetist Certification (BOC), American Occupational Therapy Association (AOTA), American Physical Therapy Association (APTA), and National Orthotic Manufacturers Association (NOMA):

> *"If a beneficiary needs a TLSO, WHO, KAFO and/or transtibial prosthesis, as deemed medically necessary and prescribed by a medical doctor, which types of members of your organization might provide services and what are their individual qualifications?"*

In response to Ms. Doolan's question, William DeToro, American Board of Certification (ABC) gave the first presentation. In his presentation he used an example of a patient requiring an L1940. Mr. DeToro noted the following items:

- Typically the patient is seen in an outpatient setting.
- The patient file make up consists of prescriptions, diagnosis, medical history, and insurance information.
- The patient should expect to receive the whole procedure, from the initial evaluation to follow-up care. (The entire O&P procedure is billed as one claim.)

In addition, Mr. DeToro also explained differences in professional duties for certified practitioners, prosthetic assistants, prosthetic technicians, orthotic assistants, orthotic technicians, and orthotic fitters. As examples he stated that the ABC certified practitioner would perform the evaluation, castings, fit the orthosis, and evaluate the fit of the orthosis. In contrast, the technician would remove the unfinished orthosis from the positive model, and finish the orthosis. The assistant could be used to remove the cast, and perform modifications/rectifications of the positive model.

Following his presentation, the following comments were noted:

- Orthotists do not require additional training in pediatrics. Schools are required to include pediatric orthotics in their curriculum and in residency programs.
- The outcome of an improperly fitted orthosis could be that the condition worsens. A patient could also have an orthosis that is fit properly but does not function properly.
- Practitioners consider neurophysiology requirements of patients.
- Technicians do not have contact with patients (they usually work in the lab doing fabrication)
- Requirements for ABC certification include a Bachelor's degree, certificate program in O&P at an NCOPE accredited institution, and 1-year of residency prior to taking the exam.
- A transtibial prosthetic patient would be provided prosthetic care. A certified orthotist would not provide this care. A certified prosthetist or certified orthotist/prosthetist would provide this care.

The second presentation was provided by Don Fedder, Board for Orthotist/Prosthetist Certification (BOC). Dr. Fedder stated that the procedures described in the ABC presentation are the same as those done by BOC—where certified practitioners do direct work with patients and technicians work in the background. BOC exams (there are three) are based on content outlines similar to ABC and he noted that the BOC tests for entire areas for O&P practice. The following comments were noted regarding the BOC presentation:

- To be eligible for BOC certification, you must have been immersed in O&P for 4 years (at least 2 years of education and training and 2 years of patient care).
- Practitioners can do fabrication themselves, use central fabrication facilities, or use technicians.
- The practitioner is considered responsible for overall patient care.

In lieu of a formal presentation, representatives from the American Physical Therapy Association (APTA) distributed a handout in response to Ms. Doolan's question for the committee to review (Attachment 6.4). Among the information provided included the following statements:

- Aides do not provide physical therapy services.
- "Fabrication" (by physical therapists) depends on a number of factors, including but not limited to the particular needs of the patient, the particular education, experience and expertise of the licensed physical therapist, the accessibility and availability of others who might provide these services, and established working relationships.

In response to the handout, the following comments were noted:
- Physical therapists do not use aides in patient care activities.
- A PT assistant is a graduate of a CAPTE (Commission on Accreditation on Physical Therapy Education) accredited 2-year program and sits for a national licensure exam (there are 7 holdout states).
- In order to get Medicare reimbursement, examination has to be done by a physical therapist.

American Occupational Therapy Association member (AOTA) Julie Kass gave a short presentation before lunch and elaborated on her presentation the next day (See Day 2).

Member Terry Supan, (State Boards) provided the committee with three handouts to review/consider:
- Illinois Orthotic, Prosthetic, & Pedorthic Practice Act – Administrative Rules (Attachment 6.5a)
- Guidelines for Training Personnel in Developing Countries for Prosthetic and Orthotic Services (Attachment 6.5b)
- International Society for Prosthetics and Orthotics Information Package (Attachment 6.5c)
- Memorandum from Terry Supan (Attachment 6.6)

In response to Ms. Doolan's question, the National Orthotic Manufacturers Association (NOMA) issued a written statement to the committee (Attachment 6.7). The statement reiterated that NOMA is comprised of orthotic device manufacturers, and is not involved in the practice of prosthetics. Additional comments made in reference to the NOMA statement included:
- To get a supplier code you have to meet supplier standards and NOMA companies would have supplier numbers.
- NOMA members do not provide care to beneficiaries.
- NOMA members are not practitioners.
- NOMA members do no manufacture prosthetic devices.

Next, the committee discussed the issue left on the table at the last meeting regarding the definition of a qualified provider (for PTs and OTs). Mike Brnicick distributed a handout explaining why the National Commission on Orthotic and Prosthetic Education (NCOPE) does not support the PT/OT claim that they are qualified by license (Attachment 6.8). Other members of the committee distributed handouts stating their position(s) on this issue (Attachment 6.9: Occupational Therapy Formal O&P Education During OT Curriculum; Attachment 6.10: National Association for the Advancement of Orthotics and Prosthetics (NAAOP) Memorandum; Attachment 6.11: Reed Smith Memorandum; Attachment 6.12: Galland, et al, Memorandum; Attachment 6.13: Board for Orthotist/Prosthetist Certification (BOC) Memorandum; Attachment 6.14: Joint Memorandum from 12 committee organizations).

As reflected in many of the attachments and comments from various committee members, a number of organizations represented on the committee felt the PT/OT

representatives presented inaccurate, or at a minimum misleading information on citations for regulatory definitions on the terms qualified PT and qualified OT. In response to this, Julie Kass, American Occupational Therapy Association (AOTA), stated that she disagreed that the referenced documents were either wrong or misrepresented the law.

In hopes of bringing the issue of PT/OT qualification to consensus, Ms. Sylvester posted the original language drafted from a caucus held at the last meeting:

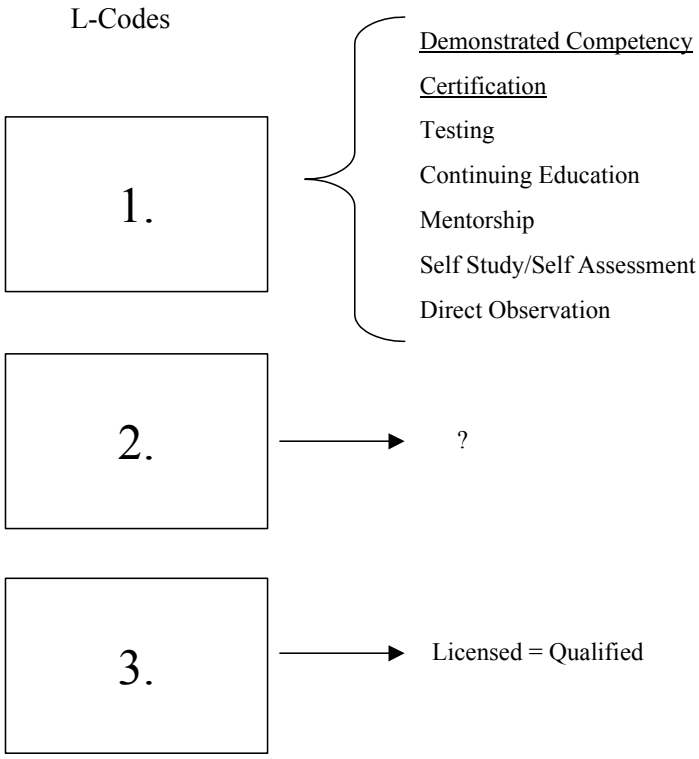
> *Every professional operating under the statute has the responsibility to ensure that he/she is competent to perform the orthotic and prosthetic services provided to an individual patient/client.*

The committee took a break to consider how it could best move towards consensus on this issue.

Upon returning from break, the group considered the following revised text:

> *Any health professional that seeks qualifications for Medicare reimbursement under Section 427 of BIPA 2000 assumes responsibility, in addition to either national certification or state licensure, to document that he/she has gained the specific competency to provide the referenced orthosis and prosthesis.*

Ms. Sylvester stated that this definition should be considered with the following L-code schematic:



The committee could not reach consensus on the new definition, nor could they agree on the assertion that there is a linear relationship between the degree of complexity of a procedure and the level of competency need by the practitioner. Other items of disagreement involved whether the proposed definition would require ABC and BOC practitioners to demonstrate competency. To obtain an accurate understanding on how divided the committee was, Ms. Sylvester asked each member to state if he/she thought a consensus was possible on this issue. The committee was split on whether or not a consensus could be reached (10 said yes and 8 said no).

When the call for public comment was made, Paddy Rossbach addressed the committee and asked that PTs/OTs not be allowed to do prosthetic work. (Attachment 6.16a)

Day 2 – April 8, 2003

The second day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics began with a presentation from Julie Kass, (AOTA), in response to Kim Doolan's question on the qualifications of service providers. As part of her presentation, Ms. Kass showed samples of various orthoses provided by OTs. Among the information provided during her presentation included the following statements:

- In over 40 state practice acts, OTs can design, fabricate, and fit orthoses.
- We (OTs) do not claim to do comprehensive O&P.
- OT scopes of practice include reference to the fabrication of orthoses.

- By OTs' code of ethics, training, professional experience, and field work, they would determine what they can provide. In some cases they may need extra training, the same way an orthotist may need extra training before doing a halo, for example.

Following the OT presentation, John Michael, American Orthotic and Prosthetic Association (AOPA), proposed that the committee consider a proposal (Attachment 6.15) offered by a morning caucus that recommended the committee look at specific L-codes to see if consensus could be reached on what base codes the OTs/PTs would and would not provide. (At first glance, he thought, of the 14 upper limb orthoses, 9 were routinely provided by OTs/PTs, 3 he would want to 3 exclude, and 2 that required more information before a decision could be made.) He proposed the committee consider the following language:

> *OTR/L is considered fully qualified to provide the following custom made, low temperature, upper limb orthoses based on specific training, testing, and expertise requirements currently in place. OTR/L is also considered fully qualified to provide all appropriate add-on L-codes to these custom made, low temperature orthoses.*

The committee took a caucus to discuss the new language. After the caucus, the following comments were offered:

- We (OTs) do low and high temperature orthoses. And we don't just do hand orthoses, we do other parts of the body as well.
- No one provides the full range of orthotics, so a discussion on comprehensive O&P is irrelevant.
- We (OTs/PTs) do more than the proposed list (offered by John Michael).
- The proposal can be modified; it doesn't preclude additional discussion.
- Each individual therapist is compelled to maintain competency for any area of their practice, so I have a visceral reaction to any list that confines what we (OTs/PTs) can and can't do.

Following this discussion the facilitators reminded the group that they had not reached consensus on two issues they considered fundamental to the negotiation—custom fabrication over a positive model of the patient and qualified provider. The group took another caucus to discuss the issue of qualified provider. As a result of the caucus, Charles Dankmeyer, Coalition of State Associations, related to the committee that the position of the O&P community is that CMS should define/determine what the terms qualified PT and qualified OT mean. Julie Kass, disagreed, stating that by putting the issue back in the hands of CMS the committee had accomplished nothing.

Seemingly frustrated, various members of the committee asked to disband the committee, move to another issue, and/or discuss the issue of qualified supplier. Others thought the remaining time could be used to share/exchange information with CMS so they will be better informed should they have to write the rule without consensus from the committee.

It was noted that the only issue the committee reached consensus on was that of prosthetics.

To allow for offline discussions, the committee took another caucus. When they reconvened, Ms. Sylvester stated that the parties had explored methods of allowing the regulatory negotiations committee to proceed and that they were able to find a method of moving the discussions forward. She expressed appreciation for their hard work and commitment to the negotiation process. She offered to prepare and agenda and send it in advance of the next meeting, scheduled May 19-20, 2003, via email.

Before the meeting adjourned, she informed the committee that member Lee Nattress was no longer with his organization, Amputee Information Exchange. To-date, the Amputee Information Exchange has not requested that another member be appointed to replace him. It is unclear, at this time, if the Amputee Information Exchange will continue to participate in the regulatory negotiation committee process.

When the call for public comment was made, a representative from the Board for Certification for Pedorthics requested that they be on the agenda for the next meeting, since the committee did not reach their item on its agenda for this meeting.

The meeting was adjourned at 3:40 p.m.

List of Attachments

Attachment 6.1	Sign-In Sheet
Attachment 6.2	Agenda
Attachment 6.3	Final Minutes Meeting #5
Attachment 6.4	American Physical Therapy Association (APTA) handout
Attachment 6.5a	Illinois Orthotic, Prosthetic, & Pedorthic Practice Act – Administrative Rules
Attachment 6.5b	Guidelines for Training Personnel in Developing Countries for Prosthetic and Orthotic Services
Attachment 6.5c	International Society for Prosthetics and Orthotics Information Package
Attachment 6.6	Memorandum from Terry Supan
Attachment 6.7	NOMA Statement
Attachment 6.8	National Commission on Orthotic and Prosthetic Education (NCOPE) handout
Attachment 6.9	Occupational Therapy Formal O&P Education during OT Curriculum
Attachment 6.10	National Association for the Advancement of Orthotics and Prosthetics (NAAOP) Memorandum
Attachment 6.11	Reed Smith Memorandum
Attachment 6.12	Galland, et al, Memorandum
Attachment 6.13	Board for Orthotist/Prosthetist Certification (BOC) Memorandum
Attachment 6.14	Joint Memorandum (from 12 committee organizations)
Attachment 6.15	American Orthotic and Prosthetic Association (AOPA) handout
Attachment 6.16a	Paddy Rossbach's Public Comment
Attachment 6.16b	Public Comment Package.

March 25, 2003

Commissioner Lynn Sylvester
Federal Mediation and Conciliation Services
2100 K Street, NW
Washington, DC 20427

Dear Commissioner Sylvester:

As per our previous communications, I believe the time has come for the Amputee Coalition of America (ACA) to present a position statement during the public comment period at the next convening of the Negotiated Rulemaking.

I would like to present the enclosed statement as President and CEO of the ACA, representing the more than 1.25 million individuals living with Limb loss in the United States. I understand the next meeting will take place at the Hilton Pikesville, Baltimore, on Monday, April 7, 2003. As I will be at a meeting in Tucson on April 5th and 6th, I have arranged to take an overnight flight into BWI arriving early that Monday morning. I will come straight to the hotel from the airport. Is there any way I can be assured of a seat in the public area?

I can be reached until April 5, at 860-435-8892, or by email at pgraspire@aol.com. I look forward to being able to present the needs of the consumer at this convening.

Sincerely yours,

Paddy Rossbach, RN
President & CEO
Amputee Coalition of America

cc. Commissioner Ira B. Lobel
Dr Hugh Hill
Douglas P. McCormack, Esq
Kurt Collier, CP

CENTERS FOR MEDICARE AND MEDICAID SERVICES
NEGOTIATED RULEMAKING COMMITTEE MEETING

PUBLIC STATEMENT
Amputee Coalition of America
Paddy Rossbach, RN
April 7, 2003

Dr Hill, Commissioner Sylvester, Commissioner Lobel and members of the Negotiated Rulemaking, thank you for allowing me to speak on behalf of the more than 1.2 individuals living with limb loss in the US.

My name is Paddy Rossbach, I am the President and CEO of the Amputee Coalition of America, the leading national non-profit consumer organization for individuals living with limb loss in this country. I am a registered nurse and have been an amputee since the age of six.

First let me say that when I heard the reason why it is now necessary for the ACA to make a position statement at these proceedings, I was absolutely astounded. In my more than 45 years practicing as a licensed registered nurse, and 59 years as an amputee, I have never encountered a Physical or Occupational Therapist who either wished, or felt that they were trained, to fit and fabricate prostheses.

For the past 19 years I have been working with amputees of all ages hand in hand with the entire team of health care professionals who prepare them to lead a functional, productive lifestyle of their choice. Each individual on that team has a unique skill for which they have been trained. It is the combination of those skills that leads to a successful outcome for the amputee. However, the surgeon must have a basic understanding of prosthetics and a close relationship with a prosthetist so that he or she can make an educated decision about the type of surgery or placement of incision to ensure a positive prosthetic outcome. In the same way physical and occupational therapists must have a basic understanding of how prosthetic components work so that they can train the amputee in their use. But that basic knowledge in no way prepares them to make the prosthesis. Of course there is a common path in the education process. As a nurse I also studied anatomy, physiology, surgical techniques etc, but does that qualify me to be a surgeon? Would anyone really want me to perform a surgical procedure on them – I don't think so. Today, with the tremendous advances in techniques and technology, health care providers are becoming more and more specialized even within their own field of expertise, and certainly would not want to practice outside of that field.

I would like to ask everyone around this table, how many of you are wearing a prosthesis? How many of you get up every day, put the cut off part of your limb into a hard plastic socket and try and maneuver around potholes, uneven ground, subway steps – or any steps for that matter – speeding taxi cabs, school playgrounds, snow and ice, and on top of that compete in the workplace with individuals who do not have a disability? How many of you know that many amputees expend 2 ½ times the energy of someone without an amputation to walk at half the pace, and although there are many reasons for this, several are simply due to poor fit and alignment of the prosthesis. Fabricating a prosthesis is not just a matter of putting a few components together like a tinker toy. The single most important part of a prosthesis is the socket, or the part the amputated limb must fit into.

Prosthetics is a very specialized field, the practitioner must be able to clinically assess each individual's specific physical and emotional needs at a particularly vulnerable time in their life. They must recommend care and technology-appropriate prosthetic components, and in addition, must design, fabricate, fit and maintain increasingly complex artificial limbs that will maximize the amputee's current and potential physical needs and activity level.

Each of us, and by us I mean amputees, has unique needs, from babies born with a limb deficiency to teenagers having an amputation for cancer, to our troops losing their limbs in combat, to the elderly losing limbs because of vascular insufficiency or diabetes. However, one need we all have in common is the need to be as active as possible, as it is well documented that people living sedentary lifestyles are at risk for a

range of secondary conditions which include: obesity, diabetes, the loss of a further limb, cardio-vascular disease, depression, back pain, and even some forms of cancer. But in order to be active we must have access to comfortable, technology-appropriate prostheses. While I have the greatest respect for the work of physical and occupational therapists – in fact I firmly believe that a successful outcome for amputees is as much due to the prosthetic rehabilitation carried out by these individuals as it is to the work of fabricating and fitting a prosthesis by the prosthetists – I do not believe they have the knowledge or the training to successfully fabricate and fit artificial limbs.

So, I leave each one of you with this question, if in the future your child contracts bacterial meningitis and loses all four limbs, or your husband, wife, mother or father suddenly becomes an amputee, who would you want to fit them with their artificial limbs, someone who has been specifically trained to do just that, a prosthetist, or someone who has been trained in the skills of rehabilitation, a physical or occupational therapist?

I, and many others in this room today, am an example of what can be achieved with appropriate care and technology. I trained as a nurse, specialized in the O.R where I frequently pulled double shifts, on my feet for 16 hours at a time. I ski, scuba dive, run marathons, show horses and recently learned to roller blade. I am a fully functional wage earning, tax paying human being – because I have benefited from the best of care. I cannot begin to imagine what my life would have been like if this were not the case. I believe everyone should have the same opportunity.

One of the teenagers with whom I worked at Sloane-Kettering wrote an essay for early admission to Harvard about how it felt to lose a leg to cancer. His definition of the word amputation was:

> *A word which connotes such extreme traumatic finality, the actual physical loss of a part of one's body, never again to be seen or felt, gone forever.*

Losing a limb is indeed a tragedy, but not being cared for by a healthcare professional trained to perform a specific intervention, such as surgery, prosthetics, rehabilitation etc is a far greater tragedy, and one that is completely avoidable.

Respectfully submitted,

Paddy Rossbach, RN
President & CEO
Amputee Coalition of America.